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Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds

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ITEM 5

CFO OVERVIEW

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ITEM 6

TAX UPDATE

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ITEM 7

GLOBAL ASSURANCE SERVICES UPDATE

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ITEM 8

CHIEF INFORMATION OFFICER UPDATE

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ITEM 9

CHIEF LEGAL AND COMPLIANCE OFFICER UPDATE

CardinalHealth

CARDINAL HEALTH CONFIDENTIAL

To: Cardinal Health Audit Committee of the Board of Directors

From: Craig S. Morford, Chief Legal and Compliance Officer

Date: October 2012

Subject: Annual Quality and Regulatory Report

This memorandum and the attached pre-read slides describe key challenges we and other healthcare companies face in the current regulatory environment and the actions we are taking to address those challenges. While the current regulatory environment has become more aggressive and less predictable, we accept this ever-changing reality and are taking actions to proactively manage our businesses accordingly. In our upcoming meeting, I will share observations and field any questions you may have about these or other regulatory matters.

Overview of Current Regulatory Environment

As Paul Keckley discussed during the August Board dinner, regulatory enforcement has become increasingly intense, especially under the current administration and particularly within the healthcare industry. Our businesses are impacted by a large number of federal, state and international agencies including DEA, FDA, HHS, NRC, OSHA, federal and state EPAs, Customs, State Boards of Pharmacy and State AGs. This Annual QRA Report will cover our management of overall quality/regulatory responsibilities, with particular focus on our two most impactful regulators from a QRA perspective – FDA and DEA.

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DEA

The DEA continues to pursue the enforcement-oriented approach it began five years ago when it launched its initial "Distributor Initiative" to address the problem of controlled substance diversion through rogue Internet pharmacies that existed at that time. Prior to the sudden emergence of the rogue Internet pharmacy problem, DEA Diversion Investigators had approached the industry with a more regulatory-oriented mindset, addressing regulatory requirements in a way that avoided unnecessary adverse impacts to the legitimate supply chain. Although fines were occasionally assessed, they were generally proportionate to the nature of the infraction and registrants understood what was expected of them. Suspension of DEA Registrations was generally reserved for registrants engaged in criminal misconduct and grossly negligent registrants with little or no control programs.

In 2007, in response to the rapid growth of rogue Internet pharmacies and corresponding pressures from the media and Congress, the DEA began shifting significant criminal enforcement resources (special agents accustomed to prosecuting street criminals and illicit drug conspiracies) from the criminal side of the DEA to their regulatory side (the DEA Diversion Control Program). Unfortunately, former criminal agents often lack the regulatory experience to appreciate the medical implications aggressive enforcement actions can have on legitimate medical patients. Through its Distributor Initiative, the DEA sought to place greater responsibility for anti-diversion diligence on pharmaceutical distributors by focusing enforcement actions on distributors, including actions against ABC (2007), McKesson (2007) and Cardinal Health (2007).

It is the view of the DEA (and Congress, based on the findings of a recent GAO report) that this initiative was successful in significantly reducing the diversion of controlled substances through rogue Internet pharmacies. Unfortunately, while diversion through Internet pharmacies has significantly declined, demand for diverted substances has not and diverters quickly shifted from use of rogue Internet sites to the use of rogue pain clinics that both prescribed and dispensed controlled substances, and, more currently, to obtaining prescriptions from DEA registered physicians and then filling them at traditional chain and other retail pharmacies used by large numbers of legitimate patients. Third-party consultants and attorneys close to the DEA continue to advise us that DEA's focus on distributors will continue. The DEA also appears to be expanding their focus to include manufacturers and large chain pharmacies. DEA registration statistics show that while there are approximately 1.3 million practitioners (prescribing doctors) (92% of total DEA registrants), 67,000 retail pharmacies (5% of total registrants) and 16,000 hospitals and clinics (1% of total registrants), there are only approximately 500 manufacturers (.04% of total registrants) and 800 distributors (.06% of registrants). Of the 800 registered distributors, the vast majority of controlled substances are distributed through a very small number of distributors, the largest of which are McKesson, Cardinal Health, ABC and a few large, self-warehousing retailers. Similarly, of the 67,000 retail pharmacies, a large percentage are chain stores owned and operated by a small number of national companies (Walgreens, CVS, Rite Aid, etc.) and grocery/variety store companies (Walmart, Safeway, Kroger, etc.). In short, the DEA will continue to pressure distributors like Cardinal Health and large national retailers directly through the threat of enforcement actions and indirectly by placing pressure on upstream suppliers. During the past year, we have received first-time due diligence requests from manufacturers who have told us they are receiving increasing pressure from the DEA to perform diligence on their distributors. DEA has also brought enforcement actions against CVS, Walgreens and Cardinal Health (2012), as well as smaller distributors including Harvard Drug Group (6/10/11), Sunrise Wholesale (6/10/11) and KeySource Medical (6/11/11). In recent months, ABC disclosed their receipt of a criminal grand jury subpoena and a DEA administrative subpoena relating to a customer in New Jersey and ABC's anti-diversion program.

In addition to the continuing threat of enforcement actions, the DEA also continues to increase the frequency of its inspections of wholesaler and manufacturer facilities. DEA requested to increase its number of diversion investigators by 60 for FY11 and another additional 50 for FY12. As is the case with the FDA, this increase has resulted in the proliferation of less experienced regulatory inspectors. Additionally, criminal agents with little knowledge of the legitimate members of the supply chain are becoming increasingly involved in regulatory investigations. These trends are reinforcing the shift from a regulatory to an enforcement mindset.

We continue to assess our program in light of these changes and the regulatory action we experienced last year, and have implemented significant enhancements to our personnel and controls. We are also attempting to work more collaboratively with the agency. We have

reached out through several avenues to initiate greater dialogue and understanding with DEA headquarters and local offices. While some DEA personnel in field divisions have engaged in dialogue with us, DEA headquarters has been unresponsive to our communications. HDMA, our pharmaceutical distribution trade association, has expressed similar experience in its efforts to engage DEA in a meaningful way on behalf of all distributors. We are committed to improving the level of engagement and collaboration with DEA and are currently focusing our efforts on engaging with the DEA where these efforts are currently most productive – at the local field level.

I will be prepared to address any questions you may have regarding this information during our meeting next week.

INTERNAL USE ONLY

2012 Annual Quality and Regulatory (QRA) Report To The Audit Committee of the Board of Directors

Craig Morford
Chief Legal and Compliance Officer
November 2, 2012

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Shift in Regulatory Landscape

- DEA: Aggressive posture continues, with particular focus on distributors and national chain pharmacies
  - CVS: (License revocation on FL stores; still in litigation phase)
  - Cardinal Health: Lakeland DC (License suspension; settlement reached; U.S. Attorneys in states of Maryland, Washington State, Tennessee and Florida exploring possibility of fines)
  - Walgreens: Jupiter DC license suspended; actions expected against 6-8 FL stores (we do not sell controlled substances to those stores)
  - ABC: ABC disclosed Criminal Grand Jury Investigation in SEC quarterly filing involving NJ Pharmacy and ABC's anti-diversion program

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FY12 and FY13 YTD Pharmaceutical Segment Regulatory Inspection Performance

Business	Agency	No. of Inspections	Outcome	Status
Pharmaceutical Distribution	DEA	10	2 Observations. Observations related to documentation. 0 SOM Observations.	
NPS and Pharmacy Solutions	Redacted - Not Responsive			
	BoP, DEA	19	7 Observations	
Redacted - Not Responsive				
PharmPak, 3PL and SPS	DEA	3 DEA (1-SPD; 3PL)	0 Observations	
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Kinray	FDA, State, DEA	2	0 Observations	
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Legend: Satisfactory | Improvement Needed | Unsatisfactory

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DEA: Major Changes to Our Anti-diversion Program to Meet Evolving Challenges

Before

- More focus on retail independent customers (considered higher risk)
- Significant reliance on Chain Customers internal systems to investigate unusual ordering patterns
- Focus on all controlled substances (equal focus on all drug families)
- Focus on suspicious customers – those most likely diverting
- Reliance on internal expertise (CAH Pharmacists) with periodic external gap assessments
- Limited interaction with upstream business partners and large downstream chain partners
- Single decision making process for most decisions (SOM Team)

Enhancements

- Increased focus on major retail chain customers
- More comprehensive review of chain customers' ordering patterns (Data analysis + Site visits)
- More focus on highly diverted controlled substance drug families
- More focus on suspicious orders regardless of our assessment of customer
- Greater reliance on external as well as internal expertise (CAH Pharmacists + former DEA Anti-diversion Experts)
- Greater interaction with upstream and large downstream chain partners
- Escalated decision making process for high risk/critical decisions
- Additional checks and balances, including committee review of higher volume customers

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DEA: Memorandum Of Agreement (MOA) Progress Update

	MOA Requirements	QRA Progress	Requirements Met?
Site Visits	• Site visits in response to Suspicious Orders for FL Customers (starting Jun. 3)	▪ Identified 13 drug families most likely to be diverted ▪ Streamlined site visit templates ▪ Visited ~85 pharmacies in FL (May 14 – Sep. 7)	✓
	• Additional inspectors for FL	▪ Contracted third party investigators ▪ Added 2 full-time FL investigators (7 total nationwide)	✓
	• Site visits in response to suspicious orders nationwide (starting Sep. 11)	▪ Established same enhanced procedures and policies nationwide on Sep. 1	✓
Establish Purchase Alert Limits (Thresholds)	• Review and enhance QRA processes for threshold setting	▪ Re-set thresholds for oxycodone and hydrocodone for ALL pharmacy customers ▪ On track to apply new threshold setting methodology by Nov. 1, 2012 to the 11 additional drug families most likely to be diverted	✓
	• Institute 2-person approval for increasing thresholds for larger volume customers for specific drug families	▪ Executed for large volume customers ▪ Developed and executing approval process for all pharmacy customers	✓
Large Volume Review Team	• Create Large Volume Review Team (LV-TAC) to perform deeper assessments of stores ordering larger volumes of higher risk drugs	▪ Formed multi-discipline team (SVP QRA, Regulatory Counsel, VP of Anti-diversion program, outside DEA advisor) ▪ Conduct weekly/bi-weekly LV-TAC review meetings ▪ Reviewed ~460 stores (~190 independent and ~270 chain)*	✓
Suspicious Orders	• Report all suspicious orders to DEA whether we believe the customers are good or bad	▪ Reported thousands of Suspicious Orders (SO) for 559 unique customers (101 in FL) for SOs nationwide* ▪ On track to execute accrual changes on Nov. 1, 2012 ▪ Developed DEA metrics-driven framework for customer profiling	✓
Due Diligence	• Enhance customer due diligence (including chains)	▪ Developed Sales Site Visit process ▪ QRA and Sales visited ~725* and ~750** customers, respectively (1,475 customers total) ▪ Terminated 126 (17 in FL) customers nationwide*	✓

*Jan. 01– Aug. 31, 2012, ** Aug. 01- Sep. 10, 2012

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DEA: Relevant Cardinal Health Program Metrics

Category	FY10	FY11	FY12	2011 / 2012 Variance
Number of pharmacy site inspections by CAH	325	498	1,475	+414 (+83%)
Number of suspicious orders reported to the DEA	30	47	3,020*	+2,973 (+6,326%)
Number of customers blocked by QRA from purchasing controlled substances	60	36	218	+182 (+506%)
Number of prospective customers blocked by QRA from purchasing controlled substances	N/A*	18	27	+9 (+50%)

* Prior to 2012, Cardinal Health followed the industry practice of focusing reports on orders by suspicious customers – those determined to be of interest to the DEA as potential diverters. Cardinal Health now reports all suspicious orders.

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